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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,321	02/17/2004	Roland Buelow	A-64360-2/TAL/NHT	1116

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,321	BUELOW ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/27/05, 4/6/05, 2/7/05,8/16/04,12/10/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this Office Action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with both these requirements in the time period set forth in this Office Action will be held non-responsive.

2. Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NO for sequences disclosed in the specification (for example, the specification at line 4 of [0010] and in the brief description of the drawings for the sequence shown in the figures.

3. Applicant's amendments filed 5/27/05, 4/6/05, 2/7/05, 12/10/04 and 8/16/04 are acknowledged and have been entered.

With regard to Applicant's amendment to the specification filed 8/16/04, the direction to amend the specification at paragraph numbers appears to be off by one paragraph number, i.e., for example, the replacement paragraph [0008] that Applicant directs be replaced, is actually paragraph [0009] in the specification, and so forth for the other replacement paragraphs.

Claims 1-10 are pending and are presently being examined.

4. Claims 5 and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP 608.01(n).

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,696,545 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the peptide of instant claims 1-7 is encompassed by claims 1-10 of '545 because the SEQ ID NO: in the '545 claims may be L or D amino acid residues and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified either the C-terminal Tyr or the N-terminal Arg to make the amide or acetate salt of the peptide because claim 1 of '545 recites "wherein the amino acid residue at least one terminus of said oligopeptide is optionally modified".

7. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,696,545 B1 as applied to claims 1-7 above and further in view of U.S. Patent No. 5,702,946 A.

Instant claims 8-10 are drawn to a pharmaceutical composition comprising the oligopeptide of any one of claims 1-7 and a pharmaceutically acceptable medium (claim 8), including an excipient (claim 9) that is mannitol (claim 10)

U.S. Patent No. 6,696,545 B1 teaches oligopeptides as enunciated supra that inhibit T cell proliferation or T cell mediated lysis, i.e., inflammation (claims).

U.S. Patent No. 6,696,545 B1 does not disclose that the peptides are in a pharmaceutical composition comprising the excipient mannitol.

U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising polypeptides that are antibodies to IL-8 that are used to treat inflammatory disorders such as organ failure, septic shock ARDS, IBD and bacterial pneumonia, said pharmaceutical compositions comprising mannitol (especially abstract and column 14 at lines 1-21).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the peptides disclosed by U.S. Patent No. 6,696,545 B1, including the ones recited in the instant claims, in a pharmaceutical composition comprising the excipient mannitol as disclosed by U.S. Patent No. 5,702,946 A.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to inhibit T cell proliferation and T cell mediated lysis, i.e., forms of inflammation, because U.S. Patent No. 6,696,545 B1 teaches oligopeptides as enunciated supra that inhibit T cell proliferation or T cell mediated lysis and U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising other polypeptides that are anti-inflammatory agents in a pharmaceutical composition comprising the excipient mannitol.

8. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 and 10 of copending Application No. 10/376,647 in view of U.S. Patent No. 5,702,946 A and WO 93/03764.

This is a provisional obviousness-type double patenting rejection.

Claims 9 and 10 of copending Application No. 10/376,647 are drawn to a pharmaceutical composition for reducing gastrointestinal toxicity induced by cytoablative therapy comprising the peptide recited in instant claim 1 and further comprising an agent that is one of an anti-diarrheal agent, an anti-inflammatory agent or an analgesic agent, and in the case of claim 10, to an anti-diarrheal agent.

Claims 9 and 10 of copending Application No. 10/376,647 do not recite wherein a pharmaceutically acceptable medium is an excipient that is mannitol, nor wherein the oligopeptide has the structural formula recited in instant claim 7, i.e., has D-amino acid residues except at position 9.

U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising polypeptides that are antibodies to IL-8 that are used to treat inflammatory disorders such as organ failure, septic shock ARDS, IBD and bacterial pneumonia, said pharmaceutical compositions comprising mannitol (especially abstract and column 14 at lines 1-21).

WO 93/03764 teaches that peptides are more stable when the D-amino acid form is used (especially page 17 at lines 27-37).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the peptide recited in claims 9 and 10 of '647 in a pharmaceutical composition comprising the excipient mannitol as disclosed by U.S. Patent No. 5,702,946 A, and to have made the peptide with any or all of the amino acid residues as the D-amino acid form.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to inhibit T cell proliferation and T cell mediated lysis, i.e., forms of inflammation, because U.S. Patent No. 5,702,946 A discloses pharmaceutical compositions comprising other polypeptides that are anti-inflammatory agents in a pharmaceutical composition comprising the excipient mannitol, and one of ordinary skill in the art at the time the invention was made would have been motivated to substitute D-amino acid residues at any or all positions in the oligopeptide because the oligopeptide in the composition of claims 9 and 10 of copending application serial no. 10/376,647 is only 10 amino acid residues in length, whereas the anti-inflammatory oligopeptide disclosed by U.S. Patent No. 5,702,946 an antibody which is much larger, hence more resistant to protease degradation, and WO 93/03764 teaches that peptides are more stable when the D-amino acid form is used.

In addition, the oligopeptides of instant claims 1-7 are encompassed by the composition comprising the said oligopeptide of copending Application No. 10/376,647, and the composition comprising the oligopeptides of instant claims 8-10 encompasses the composition of claims 9 and 10 of copending Application No. 10/376,647.

9. Claims 1-10 are directed to an invention not patentably distinct from claims 9 and 10 of commonly assigned copending Application No. 10/376,647, as enunciated supra at item #8 of this Action.

10. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/376,647, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
May 31, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No.	Applicant(s)	
	Examiner	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicant is required to provide a SEQ ID NO for the sequence disclosed in the specification at [0010].

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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